REMARKS

Applicants have canceled claims 45-49; claims 32 and 41-44 remain. Although claim 41 does not appear to be included in the rejection as presented on page 2, applicants assume from the listing on page 1, and from consideration of the rationale for the rejection that the Office meant to include claim 41 in this rejection.

Claim 32 has been amended to clarify that the claimed antibodies are not in any kind of natural environment in the event they may somehow occur in nature, and to delete the section which the Office has apparently interpreted as permitting the claim to include miscellaneous antibodies that would be immunoreactive with additional unspecified portions of the peptide. As the claim presently reads, it is clear that the antibodies are useful for detecting the specific amino acid sequence set forth in the claim. It is believed, and intended, that as the claim is presently worded, it matters not whether the specified sequence represents the complete peptide or whether it is a portion of a larger molecule. The immunoassay must detect the amino acid sequence spelled out in the claim, regardless of its environment whether included in an additional protein or not thus included.

Turning now to the rationale in support of the rejection, the Office states that the term "specifically immunoreactive" in claim 45 and thus included by implication in its dependent claims is new matter. This rationale for rejection has been obviated by cancellation of claims 45-49.

On page 3 of the action, the Office argues that the claims encompass antibodies that are useful to detect peptides that are not specifically described in the application as filed. Respectfully, this is not the case. The peptide spelled out in claim 32 is shown in Figure 8, for example, as the sequence on the bottom line of the drawing, where the N-terminal position is shown as detached from the full-length pro-peptide of the human brain natriuretic peptide so as to obtain the mature

peptide of SEQ ID NO: 49. The Office has already recognized that this peptide is specifically disclosed since the DNA encoding it is claimed specifically in U.S. 5,674,710 which issued on an ancestor with the same specification (in claim 8) and the protein is claimed specifically in U.S. 5,114,923 which issued on an ancestor with the same specification (claim 4 of that patent).

The lines quoted by the Office on pages 35 and 36 are supportive of applicants' position. The description there is clearly generic to any peptide that is described in the specification, and as applicants have shown above, the peptide sequence shown in claim 32 is described therein. The description in the bridging paragraph from pages 35-36 also makes it clear that the surrounding environment of the targeted peptide is irrelevant. Applicants fail to see how the quoted lines support the position taken by the Office.

The Office goes on to say that applicants, at the time of filing, had not isolated any antibodies useful in immunoassays to detect the amino acid SEQ ID NO: 49. Applicants are unaware that it is necessary that such antibodies actually have been prepared. The United States clearly recognizes constructive reduction to practice, and methods for obtaining antibodies to any disclosed peptide are well known. They are so well known that they need not be spelled out in detail in the application. If there is a requirement that antibodies must actually have been prepared in order to support such a claim, applicants would appreciate the Office calling their attention to such a rule or legal precedent.

Next, the Office objects to the scope of claim 32 because there is no indication of the length of the peptides of the invention and the structures of the remaining portions of the peptides are not described. Applicants again point out that as amended, claim 32 makes clear that the antibodies are directed to the amino acid sequence set forth as SEQ ID NO: 49 and not to remaining portions (if

any) of any peptide in which this sequence might be contained. Applicants are not claiming the peptides themselves, but rather antibodies that react with a specific amino acid sequence; any further sequences in the peptide are irrelevant to the invention claimed. Therefore, these objections may also be withdrawn.

Applicants appreciate the quotation from the Guidelines for Examination and the MPEP which quotations, however, do not address claims to antibodies. Antibodies are not mentioned. The attention of the Office is called to the fact that it has long been considered by the USPTO that detailed structural information (such as amino acid sequence) describing antibodies is not required. All that is required is a description of the antigen with which they react. Applicants believe that it is clearly the policy of the USPTO not to require actual reduction to practice in preparation of antibodies in order to claim them nor is it the practice of the USPTO to require amino acid sequence or other structural information concerning these antibodies.

One of many issued U.S. patents that illustrates this is U.S. 6,613,886 issued 2 September 2003 (copy enclosed). The claims in that patent are directed to an isolated antibody wherein the antibody selectively binds specified antigens. Perhaps claim 2 is the simpler of the two issued claims which simply requires that the antibody bind the amino acid sequence of SEQ ID NO: 2. It will be noted that there is nothing in the specification that in any way indicates that such an antibody has ever been prepared. The support in the specification for antibodies is limited to column 4, line 32-column 5, line 40, which merely recite art-known methods to prepare antibodies.

As a matter of fact, this is consistent with the example directed to antibodies that is provided in the Training Materials associated with these Guidelines. A copy of the discussion on antibodies is enclosed for the convenience of the Office. As noted, a specification that merely characterizes

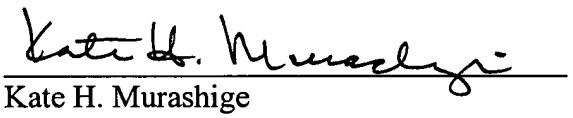
antigen X, which is shown to be novel, is fully supportive of a claim to an isolated antibody capable of binding to antigen X because the structural features of antibodies are well known. "It is also well known that antibodies can be made against virtually any protein." Thus, when discussing antibodies in particular, the USPTO itself recognizes that the characterization of the antigen to which the antibody is to be bound is sufficient to support a claim to the isolated antibody *per se*.

Applicants also cannot agree that further experimentation is required to isolate or prepare antibody compositions of the present invention. On what basis is this statement made? There is no showing that one of ordinary skill would not be able to prepare such antibodies. It is believed that it is the burden of the Office to make this demonstration; means to prepare antibodies, including monoclonal antibodies had been known for years at the time of filing of the original application in this series.

Accordingly, it is believed that the rejections as to claims 32 and 41-44 may properly be withdrawn. Applicants respectfully request these claims be passed to issue. If in the view of the Examiner a telephone discussion would helpful in, for example, rewording the claims or clearing other formal issues, a telephone call to the undersigned is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket No. 219002025213.

Respectfully submitted,

Dated: July 28, 2004 By: 

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